AMERICAN
SOCIETY FOR
MICROBIOLOGY

May 24, 1999

Dr. Harold Varmus
Director, National Institutes of Health
National Institutes of Health
Bethesda, Maryland 20892

Dear Dr. Varmus,

We are writing on behalf of the American Society for Microbiology in response to your May 5 request on the NIH web site asking for comments on the e-biomed proposal. Our reply is attached. We recognize the care and thought that went into your document and your willingness to open it for public review and discussion.

You will note that ASM has great concerns about both the value and utility of the proposed approach. However, we do believe that a frank and open debate about its merits will serve all the interested parties.

Because you have initiated discussion by posting the proposal on the NIH server, we will similarly be asking our membership for their views. We are posting the proposal and the ASM reply, and are asking ASM members to send their comments directly to you at the address indicated on your web site. We will also be incorporating the documents in all the ASM journals. In addition, we are distributing the letter to the broader scientific and public community so that our views will be on the public record. In that regard, perhaps our reply could be made a part of the material considered by the Director's Advisory Committee when it meets June 4, 1999.

Finally, we note that you have indicated a willingness to meet with us. We would be pleased to do so at your convenience.

Sincerely,
(signed by the following members of the Council Policy Committee and Editors-in-Chief)

Stuart Levy, MD, President, Tufts University School of Medicine, Boston, MA
Julian Davies, PhD, President-Elect, TerraGen Diversity, Inc., Vancouver, BC
Stanley Falkow, PhD, Past President, Stanford University School of Medicine, Stanford, CA
Martha Howe, PhD, Upcoming President –Elect, University of Tennessee, Memphis, Memphis, TN
Samuel Kaplan, PhD, Treasurer, University of Texas Medical School, Houston, TX
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Christon Hurst, PhD, CPC At-Large Member, US Environmental Protection Agency, Cincinnati, OH
Virginia Clark, PhD, CPC At-Large Member, University of Rochester Medical Center, Rochester, NY
Ronald Luftig, PhD, CPC At-Large Member, Louisiana State University Medical Center, New Orleans, LA
Marie Coyle, PhD, CPC At-Large Member, Harborview Medical Center, Seattle, WA
Roberta Carey, PhD, CPC At-Large Member, Loyola University Medical Center, Maywood, IL
Steven Douglas, MD, PhD, Editor-in-Chief, Clinical and Diagnostic Laboratory Immunology, University of Pennsylvania, Philadelphia, PA
Betty Forbes, PhD, Editor-in-Chief, Clinical Microbiology Reviews, SUNY Health Science Center, Syracuse, NY
George Jacoby, MD, Editor-in-Chief, Antimicrobial Agents and Chemotherapy, Lahey Clinic, Burlington, MA
Tom Shenk, PhD, Editor-in-Chief, Journal of Virology, Princeton University, Princeton, NJ
Vincent Fischetti, PhD, Editor-in-Chief, Infection and Immunity, Rockefeller University, New York, NY
Catherine Squires, PhD, Editor-in-Chief, Microbiology and Molecular Biology Reviews, Tufts University School of Medicine, Boston, MA
Richard Tilton, PhD, Editor-in-Chief, Journal of Clinical Microbiology, BBI-North American Clinical Laboratories New Britain, CT
Graham Walker, PhD, Editor-in-Chief, Journal of Bacteriology, Massachusetts Institute of Technology, Cambridge, MA
Judy D. Wall, PhD, Editor-in-Chief, Applied and Environmental Microbiology, University of Missouri, Columbia, MO
Alan Weiner, PhD, Editor-in-Chief, Molecular and Cellular Biology, Yale University, New Haven, CT

Response of the American Society for Microbiology

As a scientific society, the American Society for Microbiology welcomes any suggestions for improving the current process for reviewing, producing and disseminating the results of research. There are many different approaches either in use or under consideration. The new proposal for the distribution of scientific material by Dr. Harold Varmus at the National Institutes of Health is a substantial addition to the discussion. Without question, it merits serious consideration and debate. We recommend that further analysis of the pros and cons of its impact be generated via a study administered by an organization such as the National Academy of Sciences.

DESCRIPTION OF THE NIH PROPOSAL

Although many details are necessarily sketchy, the proposal essentially calls for the creation of a new electronic publishing site to be called "e-biomed." The proposal apparently envisions a single comprehensive but diverse governance structure incorporating all elements of the scientific community (scientists, writers, readers, editors), computer specialists, and funding agencies. Further, the site would operate across the entire spectrum of the biomedical sciences. Presumably because it would be funded by the government, it would publish scientific articles for "free" access by scientists and any interested member of the public.

The proposal indicates that scientific reports could be posted through one of two mechanisms. Some reports would be submitted through editorial boards similar to boards currently utilized by scientific societies. Other reports would be posted immediately without peer review after passing a relatively "simple screen for appropriateness." The proposal argues that eventually the latter process is likely to predominate due to "simplicity, flexibility and speed."

The proposal posits benefits of (1) open access and personalized journals, (2) more rapid dissemination of scientific information, (3) reduced costs to users, and (4) creation of a communal scientific site and intangibles such as a sense of scientific community.

Essentially, therefore, the proposal calls at least at the beginning stages for a new, largely government-funded and presumably government-appointed, scientific publishing entity. That entity, in turn, would freely distribute articles throughout the world over the Internet and create a "communal site" for persons interested in science.

The stated goals clearly are important. Just as clearly, the proposal requires very substantial discussion and debate as it would significantly and irredeemably modify or even replace entirely the current mechanism for dissemination of the results of biomedical research. Issues range from major public health concerns to the feasibility of its basic operating procedures. The question becomes whether the proposal would

achieve its goals and, if so, at what eventual cost to the scientific community and ultimately to the taxpayer.

SUMMARY OF ASM CONCERNS

For present purposes, ASM does not intend to engage in extended discussion of the large public policy issues or in detailed exploration of important administrative issues. Instead, we set forth an overview for further discussion and then suggest steps for detailed consideration of the proposal. Our concerns can be summarized as, (1) the significant expense associated with the administration of the proposed system and the distinct possibility that these funds will be reallocated from research, (2) the lack of quality control over the material submitted for posting, including the potential for deliberate misinformation, (3) the adverse impact on healthy competition among scientists, and (4) the involvement of NIH in an aspect of scientific publishing beyond its legislatively mandated role.

THE STRENGTHS OF THE CURRENT SYSTEM

The proposal appears to assume that there has been no or insufficient change in the process of publishing scientific articles and that attempts to incorporate new technology into scientific publishing have been insufficient. Moreover, there is a presumption in the proposal that the application of information technology to publishing has reached an endpoint. The rapid pace of change over the past few years indicates that it is impossible at this juncture to determine the future of publishing. What is clear is that a plethora of approaches will lead to more efficient and effective solutions.

In fact, most scientific societies have quickly adapted the useful aspects of information technology and are increasingly and rapidly deploying it for the advantage of both the author and the reader. A threshold question arises, therefore, whether the suggested need exists and whether, in fact, the stated goals are in the process of being reached through the existing system.

Indeed, consortia such as those organized by HighWire at Stanford University or printing groups such as Cadmus, a for-profit company, are creating virtual communities beyond the disciplines represented by single societies. In consortia, a subscriber to a single journal may have (1) access to the tables of contents and abstracts of all other journals, (2) a personalized e-mail alerting system, and (3) the opportunity to link through citations to the full text and graphics of any other article also published in electronic form by members of the consortium and, in some cases, outside it. Thus, the goal of open access and personalized journals is being achieved at the present time without intervention of government funding and without creation of a new bureaucracy.

Beyond the unique role of consortia in posting and facilitating access to articles, many scientific societies now accept manuscripts in electronic form via a web site or will do so in the near future. In turn, electronics speed the availability of the material available to reviewers. Further, many societies also now copy edit on line, capturing the

digitized material submitted by the authors. In the future, use of such production advances by existing societies is likely to increase and accelerate, thereby achieving reduced costs and expedited publication within those groups.

Further, most societies now create electronic versions of their print material and either include links to, or actually supplement it with, datasets, additional figures and photos, videos etc. As authors take advantage of technology in improving their articles, they will request support from societies. Those societies are already making the necessary adjustments. Because there are a number of societies through which articles may be published, there is internal and valuable pressure to make changes that enhance production, publication, and distribution. It therefore appears that the proposal duplicates much of what is already underway. Moreover, ASM experience indicates that not all biological science disciplines are equally ready at this point for substantial changes in the mechanisms used to disseminate their science.

In addition, the proposal's apparent emphasis on "first to publication" may have several unintended consequences; for example, it likely would lead to an increase of the least-publishable unit as authors rush material onto the general repository server, it would lead to unreviewed addenda to published papers as authors take advantage of prior peer-reviewed manuscripts, it could well lead to publication of misinformation, and it would increase the number of ethics complaints. Regarding the latter, the proposal does not even discuss issues related to investigation of ethical issues arising from claims of authorship, plagiarism, fabrication of data, etc.

Finally regarding initial publishing considerations, the proposal does not address the question of responsibility either for the future of on-line journals or for print publications. Surely, it will still be necessary and desirable to continue print publications, not the least because paper is portable, easy to read, and the only definitely reliable archival source. Will the new entity undertake print publications. If so, will the publications be free? Who will staff the effort? Will the government fund it?

PUBLIC POLICY ISSUES HAVE NOT BEEN CONSIDERED

It appears that the proposal would establish another governmental or quasi-governmental bureaucracy. The proposal states NIH will not take ownership but refers to a "governing board" comprised of representatives of the entire biomedical community and computer specialists. This leads to many questions. Who will choose this governing board? Does NIH select the board? Does a federal advisory committee with lay representatives select it? Will the Federal Advisory Committee Act apply to the board? How often is the board elected or appointed? Who reviews its performance? Is there a "vote" by the scientific community?

Realistically, it seems NIH would have to assume direct responsibility for managing this enterprise, at an eventual cost that likely may far exceed that of the individual society publishers and without performing the other functions currently conducted by individual scientific societies. The new "credentialing" effort to

denominate "appropriate" reviewers for the proposed expedited publishing process likely would consume thousands of hours reviewing thousands of applications. That cost alone would be very substantial but is dwarfed by the overhead of the actual operation of the proposed system.

Moreover, nowhere does the proposal directly address the cost issue at any level of operation. NIH would need to establish a mechanism for accepting submissions, reformatting the material, confirming the receipt with authors, sending the manuscripts out for review, acting as intermediary between authors and reviewers, receiving the final version, editing for consistency and posting with all supplemental material and hyperlinks. In addition, a multitude of peer review groups, whether they are "provided" by societies or are newly organized, will be required. As an example, ASM publishes 8 primary research journals. More than 1500 scientists serve on the editorial boards and a further 4000 act as ad hoc reviewers each year. They are expected to review 12,700 manuscripts this year.

ASM understands that proposals by Congress for new expenditures currently require offsetting cost reductions. Would budget reductions or reallocations be made at NIH as a result of this proposal? If so, would this project be the best and most efficacious use of NIH's funds? If not, how would the cost of the system be secured indefinitely? Moreover, if the funds could be made available for this project, would not the scientific community be better served by devotion of such funding to NIH's core of the enterprise, research?

From an additional public policy perspective, involvement of NIH may politicize the process of publication, thereby compromising the independence of both NIH and the individual scientists. The involvement of NIH in both grant submission and publication via e-biomed could well be a coercive influence on the selection of reviewers for the electronic server as well as on the decision by authors to publish. Who among NIH grantees would take the risk of publishing elsewhere if NIH is the principal support and overseer of an electronic publishing site? Many would argue that NIH should not control, even indirectly, both ends of the research pipeline.

Further, academic institutions use peer-reviewed publications as a key element of the tenure review process. The homogenization of publication via a single "e journal" and the concomitant disappearance of the hierarchy of journals will adversely affect the already difficult process of determining qualifications for promotion and tenure.

THE UNIQUE ROLE OF NIH

NIH has a unique role as the federal agency responsible for the funding of biomedical research. Over its history, NIH has performed outstandingly and may rightfully be considered a "jewel in the crown of government." A major contribution NIH has made is the establishment and continuing thoughtful modification of the peer review system. NIH has no complementary role for the direct dissemination of primary research findings beyond the specific authorities assigned to the Library of Medicine. On the other

hand, NIH is directed by Congress to coordinate health messages and information on new scientific discoveries through enhanced reliance on computer technology, and it could significantly extend its current efforts in this vital area.

Scientific publishing activities currently are pursued by dozens of scientific societies that also engage in a broad range of meeting, research, internship, teaching, certifying, and other functions. Publications play a vital role to these individual, special scientific communities both as a source of funds and as an integral activity binding the specific community together. Thus, while existing and rapidly evolving consortia are opening the universe of scientific publications across specialty areas, scientific communities are serving their members in ways that advance both specific interests and science as a whole. Focusing publication of science in a new, quasi-governmental, government-funded entity would appear to threaten this vital significant segment of the life science community, who now work through the scientific societies, and could lead to a monolithic entity that speaks with a single voice. A strength of the current system is the diversity of perspective even within a single discipline, such as microbiology.

This community constitutes a highly efficient marketplace and, at least for not-for-profit organizations, publishes the results of research as an integral element of their mission. Individual societies have invested substantial sums to maintain currency in the technology associated with publishing. In many instances, these sums are never recovered. The societies do this willingly because of their commitment to the fair and timely publication of research and because they are composed of authors and readers.

The Congress may misperceive the proper authority and the role of NIH in this aspect of the research process. The proposal essentially appears to suggest a government-funded competitor for the publication of scientific materials. Indeed, the competitor would be tied to the source of federal funding for biomedical research projects. Undoubtedly, publishers whose very existence would be threatened by the creation of such an entity would review existing laws and regulations in search of legal barriers. Thus, in addition to reviewing public policy issues, it is necessary to review thoroughly legal considerations regarding the creation of a government-funded and controlled publisher of scientific literature.

NEXT STEPS

All of those involved, scientists, scientific societies, for-profit publishers, libraries, and federal agencies, such as NIH, NSF, and DOE, which support life science research, should have the opportunity to offer suggestions for improving the current process for reviewing, producing and disseminating the results of research. ASM proposes that the National Academy of Sciences would be the appropriate organization to initiate a comprehensive study of the benefits and risks associated with the implementation of the e-biomed proposal. ASM would be pleased to join in this effort and to share our views.

The goal should be to identify the appropriate role of the NIH in concert with the societies and other public and private institutions to ensure that the public investment in biomedical research is successful. ASM looks forward to vigorous and thorough discussions in the interest of science.